UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,759	10/14/2003	Li Wang	P11118.00	3360

27581 7590 01/12/2006

MEDTRONIC, INC.
710 MEDTRONIC PARK
MINNEAPOLIS, MN 55432-9924

EXAMINER	
ALTER, ALYSSA M	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/684,759	WANG ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/14/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-48, 56-58 and 61-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 1-48 and 56-58, the examiner is unsure what the Applicant defines metric to be, since there is no support for such claim terminology in the specification.

As to claims 2, 16, 22, 25, 39, 45, 48, 50 and 58, they include an improper Markush group. The examiner recommends changing the claims to proper Markush format.

> A Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

As to claims 12, 35 and 54, since the claims state "disposed in a portion of the superior vena cava, a portion of the coronary sinus", the examiner is unsure if the coil electrode is disposed in a portion of the superior vena cava **and** a portion of the coronary sinus or a portion of the superior vena cava **or** a portion of the coronary sinus.

Furthermore, if the group in claims 12 and 35 are alternatives, then they are formatted as an improper Markush group. The examiner recommends changing the claims to a proper Markush format.

> Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

As to claims 13, 36 and 55, since the claims state "second electrode comprises a canister-based electrode, a canister-mounted surface electrode, a surface-mounted electrode, a ring electrode, a tip electrode, a coil electrode", the examiner is unsure if the second electrode is canister-based electrode, a canister-mounted surface electrode, a surface-mounted electrode, a ring electrode, a tip electrode **and / or** a coil electrode.

Furthermore, if the group in claims 12 and 35 are alternatives, then they are formatted as an improper Markush group. The examiner recommends changing the claims to a proper Markush format.

Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

As to claims 19-23, 42-46 and 61-64, the examiner is unsure what the Applicant means by "different electrode" in claims 19, 42 and 61. The Applicant has not specified if the electrode is a different type of electrode than its reciprocal electrode or if merely there are two separate electrodes and the first electrode not also the second electrode.

As to claims 20, 43 and 62, the examiner is unsure what the Applicant considers to comprise the different electrode. The claim states that the "different electrode comprises at least one of: a coil electrode adapted to be disposed in operative communication with a portion of a right ventricle, a portion of a superior vena cava, a portion of coronary sinus, a device canister, a surface-mounted electrode, a ring electrode, a tip electrode, an electrode forming a part of a subcutaneous electrode array". The examiner is perplexed how the different electrode can be a portion of the superior vena cava or a portion of the coronary sinus.

Furthermore, if the group in claims 20 and 43 are alternatives, then they are formatted as an improper Markush group. The examiner recommends changing the claims to a proper Markush format.

Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925). Ex parte Markush sanctions claiming a genus expressed as a group consisting of certain specified materials.

As to claims 63-64, claim 63 and 64 recites the limitation "wherein the step of providing an indication of the relatively wetter patient condition". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-13, 17-20,22, 24-36, 40-43, 45, 47-55 and 59-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Kimchi et al. (US 6,360,123). Kimchi et al. discloses an impedance sensor disposed within a blood vessel. The impedance sensor has at least two electrodes to determine the electrical impedance and obtain an impedance signal correlated with the mechanical property of the heart.

As to claim 1, 8-9, 24, 31-32, 47, 49 and 51-52, "One possible method for determining impedance in a tissue includes passing a high frequency modulated current signal through a pair of electrodes, such as, for example the electrodes 22B and 22C of FIG. 2 and low pass filtering and demodulating the voltage signal which develops across the electrodes 22B and 22C" (col. 8, lines 26-31).

Furthermore, Kimchi et al. discloses in col. 5, lines 6-25, an impedance determining unit 14 as seen in figures 1 and 2. Within the impedance measuring unit there is inherently a mathematical means for data manipulation.

Also, as to the impedance metric, Merriam-Webster Online Dictionary, metric is "a standard of measurement" {Please see Reference U}. Therefore, since impedance is measure, there is inherently a standard of impedance calculated.

As to claims 2, 25, 48 and 50, Figures 5A-5D display graphs resulting from using the impedance determining method of the present invention. As seen in the figure 5B, the impedance is continually measures and thus a portion is inherently measured during the entire PQRST waveform, inclusive of the refractory portion, an isovolumic phase, an early isovolumic phase, a late part of a systolic phase and an early part of a diastolic phase. Furthermore, since the rate of cardiac pressure change is recorded, there is also a minimum recorded.

As to claims 4-7 and 27-30, "The impedance measuring unit and the impedance sensor may be adapted for using various impedance measuring methods known in the art, including, but not limited to impedance determining methods using high frequency modulated currents or current pulses, and methods using various test current pulses"().

Therefore Kimchi et al. discloses the use of monophasic pulses, biphasic pulses and predetermined pulses.

As to claims 10, 13, 33, 36, 53 and 55, the figures display electrodes, which are coil electrodes. Specifically depicted in figure 4A are coil electrodes 32B and 32C.

As to claims 11-12, 34-35 and 54, also seen in figure 2, "the organ 18 is the heart, the blood vessel 16 is a lateral branch of the great cardiac vein (GCV). The mechanical property which is determined by measuring the intra-vessel impedance is the left ventricular pressure (LVP). When the sensor 22 is disposed within a branch of the GCV, the impedance signal which is output by the impedance determining unit 14 is highly correlated to the LVP"(col. 5, lines 53-59).

As to claims 17-18, 40-41 and 59-60, "devices such as, but not limited to pacemakers or automatic internal cardiac defibrillator (AICD) devices may be equipped with the impedance sensor and the impedance determining unit of the present invention and use them as disclosed hereinabove to monitor the LVP related impedance signal. Such a device may detect a suspected VF based on the simultaneous detection of increased heart rate sensed by an electrical sense electrode, and a flattening of the pulsatile LVP correlated impedance signal peak amplitude below a specified threshold level. Upon detection of such a suspected VF, the device may apply defibrillation pulses or other types of defibrillating therapy to the heart of the patient. Such a device may have the advantage of increasing the reliability in VF detection without adding additional leads electrodes or sensors to the device, since the impedance electrodes may be included in a pacing lead or the impedance may be measured by using existing

electrodes which are also used for such purposes of sensing or pacing in the pacemaker part of the device"(col. 15, lines 1-19). Since Kimchi et al. discloses the use of pacing/sensing electrodes, inherently when the pacemaker delivers therapy then sensing is suspended and likewise when the pacemaker system is sensing, therapy is suspended.

As to claims 19-20, 42-43, 61-62, since the first electrode is separate from the second electrode, as seen in the figures the examiner considers the first electrode to be different form the second electrode and vice versa. Specifically figure 4A displays two separate coil electrodes 32B and 32C. Furthermore, Kimchi et al. discloses that an addition set of electrodes can be used, which would be different from the first pair of electrodes.

As to claims 22 and 45, Kimchi et al. discloses in col. 1, lines 43-44, the impedance measurements can be used to estimate respiratory minute ventilation.

2. Claims 1-64 are rejected under 35 U.S.C. 102(e) as being anticipated by Stadler at al. (US Patent Publication 20040172080). Stadler et al. discloses an apparatus for detecting changes in impedance, which can be used to measure long-term fluid status variations in a patient. "Automated detection of decreases in intrathoracic impedance may lead to advanced warning of fluid overload in patients with congestive heart failure" (page 2, paragraph 26).

As to claims 1, 24, 47 and 49, the system includes two or more electrodes that delivery energy pulses to determine the impedance. Furthermore, "adjustment control that can be used to customize the output for a patient, assist in optimization of the

Signal to Noise Ratio (SNR), and avoid local muscle stimulation" (page 2, paragraph 28). Therefore the examiner considers the system to remove at least a portion of the noise from the impedance signal. Also, this system can be used in conjunction with a pacemaker or implantable defibrillation device.

As to claims 4-7 and 27-30, Stadler et al. discloses on page 6, paragraph 67, that the "output circuit 234 determines whether a monophasic or biphasic pulse is delivered".

As to claims 8-9, 31-32 and 51-52, a low pass filter is employed to determine the baseline (BL) impedance. Furthermore, "the method of updating the value of the baseline BL impedance could also be based upon lowpass filters with either the current impedance or the short term average STA impedance as the input"(page 9, paragraph 88). This BL impedance also represents the patient's "dry" impedance when no excessive fluid is present as described on page 7, paragraph 72.

As to claims 10-13, 33-36 and 53-55, "figure 6 is a schematic diagram of an implantable medical device in which the present invention may usefully be practiced according to an embodiment of the present invention"(page 4, paragraph 48). Displayed in figure 6 is a coil electrode 120 disposed in the right ventricle. Also there is a coil electrode 123 and elongated coiled defibrillation electrode 108.

As to claims 14-16, 37-39, 56-58 and 63-64, "in addition to merely alerting the patient and/or an outside entity of the detection of fluid accumulation or dehydration based on changes in impedance, a therapy may also be initiated or modified, Step 533, in response to the detection of fluid accumulation or dehydration based on changes in impedance" (page 10, paragraph 94).

As to claims 17-18, 40-41 and 59-60, Stadler et al. discloses on page 4, paragraph 48, "electrode 120 is employed for cardioversion and/or defibrillation and for sensing depolarizations". Therefore, since the electrode are capable of sensing and providing electrical therapy, inherently when the pacemaker delivers therapy then sensing is suspended and likewise when the pacemaker system is sensing, therapy is suspended.

As to claims 22-23 and 45-46, Stadler et al. discloses on page 3, paragraph 39, that other "sensors may be included in the implantable medical device for additional beneficial data generation purposes, and data therefrom is temporally matched with the impedance data to provide additionally beneficial diagnostic data". Also, described in paragraph 39, is "sensor systems or subsystems could include, for example, diurnal cycle indicators, position or posture indicators, resting indicators, heart beat cycle indicators, breathing indicators, movement indicators, and so forth, each providing a signal value that could be stored or used to trigger an activity of the implanted device". Since the system could include breathing indicators, the examiner considers the system to inherently measure a respiration rate, tidal volume and/or minute ventilation.

As to claims 19-21, 42-44 and 61-62, the figures display the multiple electrodes utilized. More specifically figure 2 discloses a schematic diagram of exemplary electrode configurations in an implantable medical device according to an embodiment of the present invention. As shown the first electrode, or em, is different from the second electrode, e2. Thus, the first electrode is a different form than the second electrode and

vice versa. Also shown in figure 2 additional electrodes eg and e1, different from the first and second electrode.

The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "impedance metric".

Claim Objections

1. Claims 22 and 45 are objected to because of the following informalities: improper punctuation. In claims 22 and 45, "comprising at least a one of: a minute ventilation metric, a respiration rate, a tidal volume for the patient, during processing of a set of impedance data" is objected to because it makes "during processing of a set of impedance data" appear to be one of the related parameters. Appropriate correction is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alyssa M Alter
Examiner
Art Unit 3762 ~~AA~~

JEFFREY R. JASTRZAB
PRIMARY EXAMINER
11/9/06